Abstract 657

TITLE: Recruitment of high-risk individuals into HIV Vaccine Trials: Barriers to Enrollment And Predictors of Participation in a Phase II Trial

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OBJECTIVE: To compare demographic and risk characteristics of people willing versus unwilling to participate in the HIV Network for Prevention Trials (HIVNET) phase II HIV vaccine trial, and to assess potential participants' reasons for declining enrollment.

METHODS: Vaccine trial participants were recruited from the HIVNET Vaccine Preparedness Study (VPS), a cohort of 4892 high-risk, HIV-negative individuals followed from 1995-97 in 8 US cities. Participants included male injection drug users (MIDU), men who have sex with men (MSM) and women at risk (WAR) through sexual behavior or drug use. VPS did not select participants based on interest in vaccine trials. Potential vaccine trial participants were screened based on randomly generated lists with over sampling of young participants and people of color, stratified by study site.

RESULTS: 222 VPS participants enrolled in the trial and 838 declined. In multivariate logistic regression, trial participation was associated with a recent self-reported exposure to HIV (OR 1.5, 95% CI 1.1-2.3) and age > 40 years (OR 2.5, 95% CI 1.3-4.8). Women (OR 0.4, 95% CI 0.2-0.9) and blacks (OR 0.4, 95% CI 0.2-0.7) were significantly less likely to enroll when compared to men and whites, respectively. Of those who declined to enroll in the trial, reasons for refusal were available for 508 (60%): 49 (43%) of MIDU screened, 508 (78%) of MSM screened, and 80 (47%) of WAR screened. Among MSM providing reasons for refusal, lack of time was the most frequently cited reason, reported by 42%, compared to 20% of WAR and 10% of MIDU ($p < .001$). Safety concerns were the most commonly cited reasons for refusal among MIDU (39%) and WAR (21%), compared to 16% of MSM ($p < .001$). Among all risk groups, 17% refused because the vaccine product could potentially produce a false-positive HIV-antibody test; 12% declined to enroll because of potential problems with insurance, legal matters, travel, or the military. Mistrust of government, belief that the vaccine product could cause HIV, and the desire to wait for a vaccine efficacy trial were each cited as reasons for refusal by 5% or fewer of participants in each risk group.

CONCLUSIONS: Aggressive recruitment efforts to enroll women, younger populations, and people of color into vaccine trials are needed. Continued efforts should be made to address HIV testing algorithms and potential harms resulting from false-positive antibody tests. Streamlining study procedures could encourage more MSM to participate in trials, while addressing safety concerns among WAR and MIDU populations may increase their trial participation.

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